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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/19/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/492,361

Applicant(s)

JENTSCH, THOMAS J.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-19, 21-45, 47 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) 12-17, 31-45, 47 and 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4, 7, 10, 11, 18, 21-30 and 59-61 is/are rejected.
- 7) ☐ Claim(s) 5, 6, 8, 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1646

## **DETAILED ACTION**

### ***Formal Matters***

Claims 1, 10 and 21 were amended in Paper No. 19, 2/28/2003. Claims 1-8, 10-19, 21-45, 47, 49-61 are pending. Claims 12-17, 31-45, 47, 49-58 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-11, 18-19, 21-30, 59-61 are under consideration.

### ***Sequence Rules***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear in Table 1, pages 10-12 of the specification but are not identified by SEQ ID NO as required.

Appropriate correction is required.

### ***Claim Objections***

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation in claim 7 wherein the polynucleotide encodes a potassium channel is broader than the recitation in claim 1 from which it depends that the

Art Unit: 1646

polynucleotide encode a KCNQ4 potassium channel. Claim 8 is objected to based on its dependence on claim 7.

Claim 7 is objected to because of the following informalities: The word "polynucleotide" is misspelled. Appropriate correction is required.

***Response to Amendment***

Applicant's amendment and arguments filed in Paper No. 19, 2/28/2003 have been fully considered but they are not persuasive, for the reasons set forth below.

***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 10-11, 18, 21-30, 59-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide having a sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for an isolated polynucleotide wherein the polynucleotide is at least 90% homologous to the nucleotide sequence set forth in SEQ ID NO: 1, or an isolated polynucleotide capable of hybridizing under the conditions set forth in claim 1 to the polynucleotide sequence of SEQ ID NO: 1, for reasons of record set forth in Paper No. 14, 2/22/2002 and Paper No. 18, 10/21/2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1646

The rejection is based upon the evidence presented in the Bowie et al. reference showing that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex, and the Mikayama et al. and Voet et al. references which demonstrates that the change of a single amino acid can radically alter protein function, and that because of this unpredictability of the protein art insufficient guidance is provided how to make or use the myriad of variant or mutated polypeptide species encoded by the claimed polynucleotides.

Applicant argues that the addition of the functional limitation has obviated the rejection. However, while the amended claim recites that KCNQ4 is an outwardly rectifying potassium channel, it does not require that the instantly claimed polynucleotide encode a polypeptide which has the function wherein it is an outwardly rectifying potassium channel. Clarification of the claim such that it was clear that the polynucleotide encoded a polypeptide which functions as an outwardly rectifying potassium channel would obviate this rejection.

Claim 10 and 21 are rejected because while the sequences in Table 1 set forth the conserved regions of the encoded polypeptide, no guidance is provided as to which residues are critical for function, and which mutations can be made while retaining function, since no function is required. The amino acid sequence of a polypeptide determines its structural and functional properties, and predictability of which amino acids can be substituted is extremely complex and well outside the realm of routine experimentation, because accurate predictions of a polypeptide's structure from mere sequence data are limited. Since detailed information regarding the structural and functional requirements of the polypeptides are lacking, it is unpredictable as to which encoding variations, if any, meet the limitations of the claims.

Art Unit: 1646

Therefore it would require undue experimentation by one of skill in the art to practice the invention as claimed without further guidance from the instant specification.

Claims 1-4, 7, 10-11, 18, 21-30, 59-61 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in Paper No. 14, 2/22/2002 and Paper No. 18, 10/21/2003.

The basis for the rejection is that these are genus claims, and that in the specification (page 5, lines 10), Applicants disclose that the mutated polynucleotide may be a polynucleotide of the invention having a nucleotide sequence encoding a potassium channel having an amino acid sequence that has been changed at one or more positions. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted

Applicant argues that the addition of the functional limitation has obviated the rejection. However, while the amended claim recites that KCNQ4 is an outwardly rectifying potassium channel, it does not require that the instantly claimed polynucleotide encode a polypeptide which has the function wherein it is an outwardly rectifying potassium channel. Clarification of the claim such that it was clear that the polynucleotide encoded a polypeptide which functions as an outwardly rectifying potassium channel would obviate this rejection.

Art Unit: 1646

Claim 10 and 21 are rejected because while the sequences in Table 1 set forth the conserved regions of the encoded polypeptide, no guidance is provided as to which residues are critical for function, and which mutations can be made while retaining function, since no function is required. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the art as to what the defining characteristics of the encoded polypeptides might be. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Art Unit: 1646

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture, or a *Xenopus* oocytes, comprising a polynucleotide with the sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for *in vivo* transfection or a mammalian oocytes comprising SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification on page 16 discloses that the nucleic acids of the current invention can be expressed in a wide variety of host cell types, including cells within a host animal and mammalian oocytes. However, there are no actual or prophetic examples that disclose how to make or use host cells that comprise a DNA sequence as set forth in SEQ ID NO: 1 in an animal or mammalian oocyte. The art, as shown by Eck & Wilson (page 81, column 2, second paragraph to page 82, column 1, second paragraph) teaches that numerous factors complicate *in vivo* gene expression which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. Since the instant disclosure does not address any of the methods necessary to make a host cell in an animal which comprises the polynucleotide of interest, therefore, the claims as written are not enabled.



Art Unit: 1646

The instant disclosure does not address any of the methods necessary to make a host cell in an animal, or a mammalian oocyte which comprises the polynucleotide of interest, therefore, the claims as written are not enabled.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The claim is drawn to a method for obtaining a substantially homogeneous source of potassium channel, but there is no isolation step after the final recited step of recovering the cultured cells.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,300,634

(Murphy et al.).

Art Unit: 1646

The '634 patent discloses a method for purification of a surface exposed antigen of H. influenzae which is conserved amongst strains (column 2 lines 34-37). Since the transfected host cell of claim 28 reads on bacterial cells, and bacterial cells transfected with an expression vector will not insert the expressed protein into the membrane, the membrane preparation of the '634 patent anticipates the claim. Since the bacterial membrane preparation encompassed by claim 28 does not contain the expressed protein, the membrane preparation of the '634 patent (see column 16, lines 40-65) is identical to the membrane preparation of claim 28, thus the membrane preparation of the '634 patent anticipates the membrane preparation of claim 28. It is noted that claim 18 is not included in the instant rejection because instant claim 28 is not truly dependent from claim 18, which is drawn to an entirely different product. The use of the short hand notation does not alter the membrane preparation claimed and serves only as a product by process type of limitation.

### ***Conclusion***

Claims 5, 6, 8, 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-4, 7, 10-11, 18, 21-30, 59-61 are rejected.

Art Unit: 1646

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 13, 2003



YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600